CV 13 - 0734

UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, THE DISTRICT OF COLUMBIA, THE STATE OF CALIFORNIA, THE STATE OF COLORADO, THE STATE OF CONNECTICUT, THE STATE OF DELAWARE, THE STATE OF FLORIDA, THE STATE OF GEORGIA, THE STATE OF HAWAII, THE STATE OF ILLINOIS, THE STATE OF INDIANA, THE STATE OF LOUISIANA, THE STATE OF MARYLAND, THE COMMONWEALTH OF MASSACHUSETTS, THE STATE OF MICHIGAN, THE STATE OF MINNESOTA, THE STATE OF MONTANA, THE STATE OF NEVADA, THE STATE OF NEW JERSEY, THE STATE OF NEW MEXICO, THE STATE OF NEW YORK, THE STATE OF NORTH CAROLINA, THE STATE OF OKLAHOMA, THE STATE OF RHODE ISLAND, THE STATE OF TENNESSEE, THE STATE OF TEXAS, THE COMMONWEALTH OF VIRGINIA, THE STATE OF WASHINGTON, THE STATE OF WISCONSIN,
EX REL. DENNIS J. COTTER,

[UNDER SEAL],

Relator,

v.

RIDGEWOOD DIALYSIS CENTER, NEPHROLOGY FOUNDATION OF BROOKLYN EAST IN BROOKLYN, NEWTOWN DIALYSIS CENTER, INC, FRESENIUS MEDICAL CARE NORTH AMERICA, AND DIALYSIS CLINIC, INC. [UNDER SEAL]

Defendants.

CASE NO.:

FILED UNDER SEAL

PURSUANT TO 31 U.S.C. § 3729 ET SEQ.

DO NOT PLACE IN PUBLIC RECORD

JURY TRIAL DEMANDED

ROSS, J.

COMPLAINT FOR DAMAGES UNDER THE FEDERAL FALSE CLAIMS ACT AND THE FALSE CLAIMS ACTS OF VARIOUS STATES AND DEMAND FOR JURY TRIAL

This is an action against Defendants Ridgewood Dialysis Center, Nephrology Foundation of Brooklyn East in Brooklyn, Newtown Dialysis Center, Inc., Fresenius Medical Care North America, and Dialysis Clinic, Inc. (collectively Defendant Dialysis Centers or Defendants) for engaging in an illegal scheme by which they falsely certified in their billing records and to the Federal Government that they were providing the requisite standard of care to patients with end stage renal disease (ESRD) when they were not. Defendants' actions harmed those patients and in some cases hastened those patients' deaths in order to improve Defendants' corporate profits. Specifically, Defendants billed Medicare and other state and federally funded health insurance programs for (1) overdosing ESRD patients with too large a dose or too many doses of the drug Epogen; (2) over-treating ESRD patients whose hematocrit level exceeded 36% with Epogen; and (3) receiving kickbacks in the form of vial over fills from Amgen, Inc. (Amgen) the manufacturer of Epogen. From 1997 to 2010, the vast quantities of Epogen used by Defendants herein to overdose and over-treat ESRD patients cost Medicare as much as $1.06 billion dollars, and the additional medical care required for ESRD patients who were the victims of Defendants' overuse of Epogen cost Medicare an additional $5.5 billion dollars.

At all times relevant to this complaint, Defendants' billings and other submissions to the Federal Government contained false certifications made by Defendants with regard to medical necessity, standard of care and patient need as well as with regard to the receipt of discounts, rebates and prohibited remuneration by Defendants. Defendants' conduct was in knowing and in direct contradiction of federal and state health care provider laws and certifications requiring

Defendants to provide services that meet the standard of care, as well as the FDA approved label, DHHS and CMS guidelines, the relevant medical compendia and the overwhelming weight of medical and scientific research regarding the appropriate use of Epogen.

This action is brought pursuant to the Federal False Claims Act, 31 U.S.C. §§ 3729-3733, et seq. and its state law counterparts. It arises from the results of practice patterns research conducted independently by Relator Dennis J. Cotter, MSE ("Relator" or "Cotter"), in connection with dialysis center utilization of and billing practices for the drug Epogen by Defendants.

Specifically, Relator complains that fraudulent conduct by and on behalf of Defendants resulted in the illegal and knowing overdosing and over-treating of ESRD patients with Epogen without regard to medical necessity, standard of care and patient need, or the deadly risks associated with the use and overuse of Epogen. As a result, claims made by Defendants to federal and state funded health insurance programs, including Medicare, Medicaid, The Railroad Retirement Medicare Program, Federal Employee Health Benefit Plans, TRICARE, The Veteran's Administration, The Indian Health Service and State Legal Immigrant Assistance Grants were false, as defined by 31 U.S.C. § 3729 and the analogous state false claims acts, in that they were submitted for reimbursement for the drug Epogen which was administered in amounts that exceed the FDA approved dosage and treatment levels.

Moreover, those excessive amounts can be directly linked to increases in adverse health effects for patients requiring hospitalizations, including increased risk of death and hastened death, as well as the increase in medical care costs per patient due to those adverse health effects and billed by Defendants to federal and state funded health insurance programs.

The misconduct of Defendants directly resulted in their unjust and illegal enrichment at

the expense of federal and state funded health insurance programs. Through this action, Relator seeks to recover damages and civil penalties arising from Defendants' false and improper claims that were submitted for payment to federal and state funded health insurance programs.

This case is brought by Relator by and through his undersigned attorneys, on behalf of himself, the United States of America, the District of Columbia, the State of California, the State of Colorado, the State of Connecticut, the State of Delaware, the State of Florida, the State of Georgia, the State of Hawaii, the State of Illinois, the State of Indiana, the State of Louisiana, the State of Maryland, the Commonwealth of Massachusetts, the State of Michigan, the State of Minnesota, the State of Montana, the State of Nevada, the State of New Jersey, the State of New Mexico, the State of New York, the State of North Carolina, the State of Oklahoma, the State of Rhode Island, the State of Tennessee, the State of Texas, the Commonwealth of Virginia, the State of Washington and the State of Wisconsin (collectively Plaintiff States). Relator avers as follows for his Complaint against Defendants based upon personal knowledge, independent research, and relevant documents.

I. INTRODUCTION

1. From 1997 to 2010, Defendants violated the standard of care for ESRD patients by overdosing and over-treating some anemic adult dialysis patients with prodigious amounts of the drug Epogen to the extent that such medically unnecessary usage exceeded both the FDA recommended dosage level and target treatment levels well beyond the bounds of documented clinical usefulness, as clearly specified in the FDA approved product label. Defendants then falsely certified in their billing records and other certifications to the Federal Government that they were meeting the requisite standard of care for these same patients and as a result received payments from Medicare and other state and federally funded health insurance programs for

these medically unnecessary services. Defendants also received kickbacks from Epogen's manufacturer Amgen in the form of vial over fills, the contents of which they also provided to patients and billed for and received payment from Medicare and other state and federally funded health insurance programs.

2. The overdosing and over-treating of dialysis patients not only wastes tax dollars, but it also harms patients by increasing their risks of mortality and other adverse health events, necessitating otherwise unnecessary hospitalization. These increases in the risks of mortality and other adverse health events in turn cause additional financial harm to federal and state funded health insurance programs because the additional health care costs associated with the increase in services needed to treat these adverse events are born by those programs.

3. Relator estimates that over 90% of kidney dialysis patients receive government funded health insurance. This federally sponsored kidney treatment program has been the single most costly expenditure for Medicare for the past two decades.

4. Epogen, manufactured by Amgen, Inc., is the brand name for epoetin alfa, a synthetic form of the hormone erythropoietin. Epogen aids in the production of red blood cells (RBC), and is used in the treatment of severe anemia commonly associated with end stage renal disease (ESRD) or kidney disease. Epogen is used to prevent or lessen the need for ESRD patients to undergo RBC transfusions which carry risk, particularly if the patient is to successfully undergo kidney transplantation.

5. Defendants are federal and state certified dialysis centers in the business of providing dialysis services to patients who suffer from ESRD. Defendants are authorized to care for the beneficiaries of federal and state funded health insurance programs. All Defendants use

Epogen to treat dialysis related anemia for the purpose of avoiding the use of RBC transfusions for their patients.

6. Relator Dennis J. Cotter, is a biomedical engineer who independently discovered overdosing and over-treating of the drug Epogen by Defendants. His findings, which form the basis of the allegations in this complaint, are based on long established expertise, his research, and insight regarding ESRD anemia management practices patterns and resulting patient outcomes.

II. PARTIES

A. Relator

7. Relator Dennis J. Cotter, MSE is a biomedical engineer with extensive experience studying health care policy, treatment and outcomes. Relator Cotter is a recognized expert in the treatment of anemia in kidney dialysis patients, including the use of Epogen to treat patients suffering from ESRD. Specifically, Relator Cotter has been at the forefront of research regarding the use of Epogen and his work has led to modifications to the FDA approved label for Epogen, including clarification of the proper dosing of Epogen, clarification of the proper target hematocrit range, and expanded warnings regarding the adverse effects associated with the use of Epogen. Relator is a resident of Bethesda, Maryland. He is the original source of the allegations contained in this Complaint.

8. Relator received his Master's degree in Biomedical Engineering from Arizona State University in 1974. From 1976 to 1979, Relator was employed as a biomedical engineer for the Food and Drug Administration (FDA). From 1979 to 1983, Relator was employed as a biomedical engineer at the Department of Health and Human Services' National Center for Health Care Technology (NCHCT), and the National Center for Health Services Research

(NCHSR). While at NCHCT and NCHSR, Relator participated in 36 evaluations of new health care technologies for purposes of Medicare coverage determinations.

9. From 1983 to the present, Relator has served as the Director of Technology Diffusion Associates (TDA), a company that provides third-party payor and reimbursement assistance for new and emerging medical technologies. In this capacity, Relator was responsible for designing and implementing the spillover analysis of Epogen for use by Ortho Pharmaceuticals in the lawsuit and subsequent arbitration between Ortho Pharmaceutical Corporation and Amgen, Inc. over the 1985 licensing agreement entered into by both companies.

10. Relator is the founder and President of Medical Technology and Practice Patterns Institute (MTPPI), a nonprofit organization established to conduct research on the clinical and economic outcomes of health care technologies. Relator currently serves as the principal investigator on an MTPPI research project entitled: "Human Recombinant Erythropoietin Utilization in the Medicare and Non-Medicare Patient Populations." Since 1992, findings from this and other MTPPI research projects concerning the use of Epogen have been reported in 30 peer-reviewed medical journal papers.

11. Relator Cotter has served as the principal investigator or co-principal investigator on numerous studies regarding the use and clinical effectiveness of Epogen therapy for dialysis and pre-dialysis related anemia. Relator is frequently asked by publishers to review manuscripts related to Epogen therapy, including by the publishers of the following journals: Kidney International, the American Journal of Kidney Diseases, Journal of the American Society of Nephrology, the Clinical Journal of the American Society of Nephrology and Health Affairs.

12. Relator has served as a senior analyst for the Congressional Prospective Payment Assessment Commission studying the inclusion of new technologies in the Medicare DRG

hospital payment system and has conducted independent healthcare research and analyses at Georgetown University's Institute for Health Policy Analysis. He also has served as an expert witness on numerous occasions including during arbitration in Ortho Pharmaceutical v. Amgen (spillover litigation), at a hearing before the House Ways and Means Committee on the use of Epogen in the ESRD dialysis patient population, before an FDA advisory panel meeting on risks related to high Epogen doses, and has been hired as an expert consultant to quantify damages to the Medicare system in a recently settled qui tam case, United States of America, ex rel. Woodard v. DaVita, Inc. (Civil Case No. 1:05-CV-00227) (E.D. Texas).

B. Defendants

13. Defendants Ridgewood Dialysis Center (Ridgewood), Nephrology Foundation of Brooklyn East in Brooklyn (Nephrology Foundation), Newtown Dialysis Center, Inc. (Newtown), Fresenius Medical Care North America (Fresenius), and Dialysis Clinic, Inc. (DCI) are federal and state certified dialysis centers in the business of providing dialysis services to patients who suffer from ESRD in the eastern district of New York, as well as elsewhere in the United States. Defendants are authorized to care for the beneficiaries of federal and state funded health insurance programs. All Defendants use Epogen, a synthetic hormone that aids in the production of RBCs to treat dialysis related anemia for the purpose of avoiding the use of RBC transfusions in their patients, thus limiting the patients' exposure to the risks inherent in RBC transfusions.

14. Relator has discovered that Defendants both overdose and over-treat anemic dialysis patients thereby deviating from the FDA-approved product label recommended dosages, treatment targets, and appropriate practice standards. Overdose is defined by the drug's stated limitation which has appeared in the product label since 1989, i.e. administering Epogen above

300 Units/kg three times per week, a level above which the drug provides no therapeutic effects; its use in this regard is independent of the level of the patient's hematocrit (Hct) level at the time of treatment. Over-treat is defined by the drug's stated limitation which has appeared in the product label since 1989, i.e. administering any amount of Epogen to elevate a patient's Hct above a 36% level. Subsequently, Defendants billed for these overdoses and over-treatments to federal and state funded health insurance programs. Morcover, such overdosing and over-treating of patients with Epogen by Defendants caused harm to patients resulting in those patients requiring additional medical services, i.e., hospitalizations -- services which were also billed to federal and state funded health insurance programs.

15. Defendant Ridgewood is incorporated in the state of New York. It is a for profit dialysis center located in Ridgewood, New York.

16. Defendant Nephrology Foundation of Brooklyn East is incorporated in the state of New York. It is a nonprofit dialysis center located in Brooklyn, New York.

17. Defendant Newtown is incorporated in the state of New York. It is a for profit dialysis center located in Astoria, New York.

18. Defendant Fresenius is a subsidiary of Fresenius Medical Care AG, a German Corporation. Fresenius is incorporated in the state of Massachusetts, and its headquarters are in Waltham, Massachusetts. Fresenius operates 2,060 clinics nationwide, including 13 clinics located in the eastern district of New York.

19. Defendant DCI is incorporated in the state of Tennessee. It is a nonprofit organization and its headquarters are located in Nashvillc, Tennessee. DCI operates 210 dialysis clinics nationwide, including 4 clinics located in the eastern district of New York.

III. JURISDICTION AND VENUE

20. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, 28 U.S.C. § 1367 and 31 U.S.C. § 3732, the last of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730. Under 31 U.S.C. §3730(e) as amended, there has been no statutorily relevant public disclosure of the "allegations or transactions" in this Complaint. Relator, moreover, qualifies under that section of the False Claims Act as an "original source" of the allegations in this Complaint even had such a public disclosure occurred.

21. Upon the filing of this complaint, Relator shall concurrently serve the complaint and a statement summarizing known material evidence and information related to the complaint, in accordance with the provisions of 31 U.S.C. § 3730(b)(2) upon the Attorney General of the United States, the United States Attorney for the Eastern District of New York, and the offices (or other State offices designated by statute) of Plaintiff States' Attorneys General. The disclosure statement is supported by material evidence. Because the disclosure statement includes attorney-client communications and work product of Relator's attorneys, and is submitted to the Attorney General and to the United States Attorney in their capacity as potential co-counsel in the litigation, the Relator understands this disclosure to be confidential and the initial disclosure statement and all documents provided therewith, and all supplements thereto, are incorporated herein by reference.

22. This Court has personal jurisdiction and venue over the Defendants pursuant to 28 U.S.C. §§ 1391(b) and 31 U.S.C. § 3732(a) because those sections authorize nationwide service of process and because Defendants have minimum contacts with the United States. Moreover, Defendants can be found in, reside in, and transact business in this District. This Court has

supplemental jurisdiction over the State law claims pursuant to 28 U.S.C. § 1367(a).

23. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) because Defendants transact business in this judicial district, and acts proscribed by 31 U.S.C. § 3729 have been committed by Defendants in this District. Therefore, venue is proper within the meaning of 28 U.S.C. § 1391(b) & (c) and 31 U.S.C. § 3732(a).

IV. BACKGROUND

A. Kidney Dialysis

24. Hemodialysis (HD) is a process for removing waste and excess water from the blood, and is used primarily to provide an artificial replacement for lost kidney functions in people with renal failure. Hemodialysis treatments replace some of these functions through diffusion (waste removal) and ultrafiltration (fluid removal). Dialysis is used for those patients with chronically worsening kidney function–a state known as chronic kidney disease stage 5 (referred to herein as chronic renal failure or ESRD).

25. Peritoneal dialysis (PD) is a process that uses the patient's own body tissues inside the abdominal cavity as a filter. A dialysis catheter is surgically placed through the abdominal wall that allows a special fluid to flush the abdominal cavity. When the treatment is complete, the fluid is removed through the catheter. The PD technique serves as a filter between fluid and the bloodstream allowing waste products and excess water to be removed from the body.

26. The number of people in the United States receiving hemodialysis (the most common type of kidney dialysis) grew from 225,000 in 1997 to 375,000 in 2008. Today, there are 5,069 dialysis centers in the United States, including Defendants, which treat adult hemodialysis patients. Medicare pays for dialysis services at a composite rate that was first implemented in 1983. This rate has changed minimally in the last 20 years, with the real dollar

value, prior to 2008 rate increases, actually declining by 65%.

B. Epogen - Generally

27. The FDA approved Epogen in 1989. Prior to FDA approval, approximately 16% of federally insured ESRD patients nationwide required one or more RBC transfusions, but by 2000, well over 95% of ESRD patients nationwide received Epogen, making it the largest single Medicare drug expenditure from 1994 to the present.

28. Epogen is the brand name for epoetin alfa, a glycoprotein manufactured by Amgen through recombinant DNA technology, which stimulates red blood cell production. The same epoetin alfa product manufactured by Amgen is also marketed and distributed for non-dialysis use by Ortho Biotech, L.P., a subsidiary of Johnson & Johnson, under the proprietary name Procrit.

29. Epogen was approved by the FDA in June 1989, for the following indication: "treatment of anemia associated with chronic renal failure, including patients on dialysis (end stage renal disease) and patients not on dialysis. Amgen's patent on Epogen expired in 2005.

30. Epogen is used in the treatment of severe anemia commonly associated with ESRD or kidney disease. The metrics used to determine whether a patient is anemic are hemoglobin levels (abbreviated as "Hgb") and hematocrit levels (abbreviated as "Hct") determined through a blood test. The relationship between Hgb and Hct values is defined as follows: Hct = 3 x Hgb level.

31. Epogen can be administered either intravenously (IV) usually through the extracorporeal blood lines used in dialysis or subcutaneously (SC) via hypodermic needle injection under the skin. Generally, ninety percent of all dialysis patients receive dialysis treatment by hemodialysis (HD) and receive Epogen via IV injection. The remaining ten percent

of dialysis patients receive peritoneal dialysis (PD) and Epogen by SC injection. The two routes of drug administration offer different pharmacokinetic properties. The SC injected amount stays in the body for a longer period of time requiring up to 50% less of the drug compared to the same IV amount to achieve the hematocrit change.

32. Patients receiving Epogen have been described as either Epogen responders or Epogen non-responders. Epogen responders are those patients for whom Epogen effectively raises their Hgb/Hct levels, and Epogen non-responders are those patients for whom Epogen does not raise their Hgb/Hct levels as intended, thereby requiring very large doses.

33. Because nearly all ESRD patients experience anemia as a complication of their illness, Defendants administer Epogen to virtually all their patients, most of whom require regular dialysis treatment. Epogen is administered to dialysis patients by dialysis center personnel three times per week.

34. Amgen produces and sells Epogen to Defendants in preservative-free, single-use vials and also in preserved vials intended for multiple uses/patients. The vials contained between 10% and 20% volume over fill that was billed to federal and state funded health insurance programs by Defendants over the period of the complaint, and thus constituted kickbacks received by Defendants and paid for by federal and state funded health insurance programs in violation of the Anti-Kickback Statute. Defendants receipt of these vial over fills from Amgen and billing of the same to federal and state funded health insurance programs also violates federal regulations that prohibit Defendants from billing Medicare for services or supplies which do not represent an expense incurred by them. 42 C.F.R. 409.13 (1993).

C. Reimbursement for Epogen by Government Funded Health Programs

35. On October, 30, 1972, Section 2991 of Public Law 92-603 extended Medicare

coverage to Americans under 65 years of age with chronic kidney disease who are in need of dialysis or a kidney transplant. As a result, this entitlement is nearly universal, covering well over 90% of all U.S. citizens with chronic kidney disease.

36. The Centers for Medicare & Medicaid Services (CMS) administer the Medicare program. In order to ensure the standard of care for its beneficiaries, CMS looks to the states to provide oversight of dialysis centers, including Defendants, by instituting one or more of the follow compliances processes: accreditation, credentialing, licensure and/or certification. In New York, for example, dialysis centers are licensed under Article 28 of the Public Health Law and the specific state regulations regarding ESRD patients can be found in Title 10 NYCRR§§ 751 -757. Federal-state coordination of responsibilities provides the necessary oversight of dialysis centers to ensure that they provide "reasonable and necessary" services to Medicare recipients. Importantly, CMS historically has recognized clinical practice standards and information contained in FDA approved product labels as the basis of the "standard of care."

37. In his independent analysis of Medicare claims data for the period 1997 to 2010, Relator Cotter has observed numerous instances where Defendant Dialysis Centers have violated the standard of care for ESRD patients as described above, yet falsely certified in their billings and other certifications to the Federal Government that they provided the requisite standard of care. Defendants' management practices, not only violate the requisite standard of care, but are also outside the bounds of both anemia management clinical practice standards and the FDA approved product label for Epogen. Defendants' actions have placed their patients at increased risk for cardiovascular and other mortality events necessitating additional hospitalization for those patients which would not have otherwise been needed and which is also billed to federal and state funded health insurance programs, including Medicare.

38. For the time period at issue, 1997 to 2010, payments for dialysis sessions for the treatment of ESRD were capped by Medicare at a bundled or composite rate. However, the Federal Government paid separately for certain dialysis-related drugs, including Epogen and the products used to administer it, based on the dose and frequency of administration.

39. Because the Federal Government reimbursed dialysis clinics for ESRD injectable drugs outside of the composite rate, Defendants' administration of drugs such as Epogen was a source of additional revenue to them. Thus, it was in Defendants' financial interest at least until 2011, to maximize both the number of treatments and the dosage levels of Epogen. In fact, Epogen payments by Medicare empirically have been the second-largest revenue source of for-profit dialysis facilities' revenue income, estimated to be approximately 25% or more of income for some Defendants.

40. Since 1994, Epogen therapy has been the largest single Medicare drug expenditure. In 2004 alone, Medicare paid more than $1.8 billion for Epogen therapy, which was a 17% increase from the 2003 expenditures. During that same period, Epogen treatments comprised 11% of all ESRD costs to Medicare.

41. The financial incentive for Defendants to use Epogen was magnified in a number of ways, including: (1) through discounts and rebates provided by Amgen to large volume Epogen users; (2) by the fact that over time the cost of Epogen to Defendants decreased, thereby increasing Defendants' profit margin on the drug; and (3) by the provision of free Epogen in the form of vial over fills provided to Defendants by Amgen and billed by Defendants to federal and state funded health insurance programs. Bulk purchases, use of over fill, and over-utilization of Epogen resulted in savings to Defendants experienced as increased earnings and profits.

Importantly, none of those savings were passed on to government funded health programs as required by law.

42. Under Section 153(a) Public Law 110275, of the Medicare Improvement for Patients and Providers Act of 2008 (MIPPA), Congress mandates that the Centers for Medicare and Medicaid Services (CMS) implement a payment system under which a single payment is made to providers of renal dialysis. In 2010, in response to MIPPA, CMS began bundling its payments for Epogen into the ESRD Prospective Payment System (ESRD PPS) composite rate payment. At that time, Congress assumed that Epogen use would at least stay constant and not decrease, because the population requiring kidney dialysis had not decreased and because no major competitor to Epogen had been introduced into the market during that time. Instead, the inclusion of Epogen payments into the ESRD PPS composite rate resulted in an almost immediate decrease in Epogen sales nationwide by 29% between January 2011 and December 2012. This abrupt decrease in Epogen sales speaks volumes about its historic overuse and the lack of medical necessity for such overuse by the dialysis industry that took place during the pre-ESRD PPS time period 1997 to 2010. It also indicates that during the same time period, 1997 to 2010, Defendants received $ 1.06 billion for the provision of medically unnecessary Epogen services that violated the established standard of care for ESRD patients.

43. Since implementation of ESRD PPS on January 1, 2011, the dialysis industry, including Defendants, has received a windfall of approximately $ 1.594 billion through 2012. This occurred because Congress included in the fixed ESRD PPS payment or composite rate the cost of providing Epogen to ESRD patients based on the amount historically used for ESRD patients. However, once Epogen treatments were included in the composite rate and thus became a cost for Defendants instead of an income stream, Defendants dramatically reduced

their use of Epogen for ESRD patients and shifted back to the use of RBC transfusions, a service which is not included in the composite rate, and for which Defendants can bill Medicare separately. USRDS reports that RBC transfusions have increased nationwide by 25% in 2011 when compared to 2010. Ironically, the principal purpose of appropriate use of Epogen was to avoid the risks related to exposing patients to RBC transfusions.

44. Moreover, because of the longer half-life of Epogen administered subcutaneously to PD patients, those patients require less Epogen than HD patients. As such, one would assume that overdosing and over-treating PD patients would not occur. To test whether providers overdosed or over-treated PD patients, Relator Cotter analyzed Medicare claims to determine the amount of Epogen given to PD patients. Surprisingly, he found a significant amount of claims documenting medically unnecessary practice patterns. Specifically, between 1997 and 2010, Relator Cotter found 30,044 claims that exceeded either the 300U/kg TIW or the Hct>40% medically unnecessary thresholds, costing Medicare $20 million for Epogen services and $143 million in hospital costs related to Epogen overdosing and over-treating.

D. Epogen - FDA Labels

45. The FDA approved label for Epogen has consistently provided appropriate Epogen dosages and hematocrit treatment targets. The dosages described in the label have not changed since Epogen's initial approval. Likewise, the hematocrit treatment target range described in the label has also been consistent since Epogen's initial approval.

46. Since its original approval in 1989, the FDA Epogen product label has carried the following statement: "The rate of hematocrit increase varies between patients and is dependent upon the dose of EPOGEN®, within a therapeutic range of approximately 50 to 300 Units/kg

TIW [three times (or administrations) per week abbreviated as TIW]. **A greater biologic response is not observed at doses exceeding 300 Units/kg TIW.**..."(emphasis added).

47. The 1989 FDA approved package insert or label provides the parameters for Epogen dosage during much of the time period at issue. The label provides for a starting dose of 50 to 100 units per kilogram for adult patients, administered three times per week. For a 175 pound adult male, this would amount to a starting dosage of between 4,000 and 8,000 units, three times per week.

48. The 1989 FDA Label provides that Epogen should be utilized for adult chronic renal failure (CRF) patients to bring the patient's hematocrit to within a target range of between 30% and 33% (corresponding to a hemoglobin level of 10 to 11 g/dL). Under the 1989 FDA label, providers are required to monitor patients regularly and must reduce the dosage as the patient's hematocrit level approaches 33% or increases by more than four points in any two week period. When the patient's hematocrit reaches 30 to 33%, the dosage should be decreased by approximately 25 units/kg "to avoid exceeding the target range."

49. The 1989 FDA Label dictated that, as the hematocrit level approaches or exceeds 36%, Epogen treatment should be suspended until the patient's hematocrit decreases to the target range of 30 to 33%, and upon re-initiation, the dosage should be reduced by approximately 25 units/kg.

50. The 1995 FDA Epogen label modified the suggested target range of hematocrit to 30 to 36%. The 1995 FDA label called for a reduction in Epogen dosage as patients' hematocrit levels approach 36% or when hematocrit increases by more than four points in a two-week interval. The 1995 FDA label specifies:

> If the hematocrit is increasing and approaching 36%, the dose should be reduced to maintain the suggested target hematocrit range. If the reduced dose does not stop the rise

> in hematocrit, and it exceeds 36%, **doses should be temporarily withheld** until the hematocrit begins to decrease, at which point therapy should be reinitiated at a lower dose. (Emphasis added).

As with the 1993 FDA Label, the 1995 label requires that Epogen dosage must be individualized to maintain each patient's hematocrit within the suggested target range.

51. In November 2007, the FDA added the following product label warning box to Epogen's package inserts:

> Use the lowest dose of EPOGEN® that will gradually increase the hemoglobin concentration to the lowest level sufficient to avoid the need for red blood cell transfusion (see DOSAGE AND ADMINISTRATION).

Early that year, in March of 2007, Relator Cotter had made a presentation to staff members from the FDA highlighting the risks to patients associated with high Epogen doses.

52. Likewise, following a September 11, 2007, presentation delivered by Relator Cotter to the FDA's Cardiovascular and Renal Drugs Advisory Committee, and Drug Safety and Risk Management Advisory Committee regarding the risks related to high Epogen doses, the FDA required the manufacturer to develop and distribute an Epogen medication guideline that included the following introductory statement:

> This Medication Guide does not take the place of talking to your health care provider about your medical condition or your treatment. Talk with your health care provider regularly about the use of Epogen and ask if there is new information about Epogen.
> **What is the most important information I should know about Epogen?**
> Using Epogen can lead to death or other serious side effects.

E. <u>Epogen - CMS/DHHS Guidelines for Epogen Use and Payments</u>

53. The CMS and DHHS Guidelines for Epogen use have always been consistent with the FDA approved label.

54. On February 1, 1997, the Department of Health and Human Services (DHHS) issued a Program Memorandum with the following observations and procedure consistent with

the FDA label for Epogen:

> ESRD patients with symptomatic anemia considered for EPO therapy should be treated until the hematocrit reaches a target range of 30 - 36%. As the hematocrit approaches 36%, administration of EPO should be reduced temporarily. The dosage of EPO required to maintain target hematocrit levels is subject to individual patient variation and should be titrated according to patient response, with a goal of not exceeding a hematocrit level of 36%.
> Effective immediately, but no later than July 1, 1997, begin calculating EPO payments based on a 90-day rolling average hematocrit measurement for ESRD patients whose hematocrit levels are greater than 36%. . . . If the average of the 90 days of readings is 36.5% or less, pay for EPO. If the hematocrit level exceeds 36.5%, **deny** payment for EPO.

55. In March 1998, having received more complaints and appeals than it could process efficiently, CMS modified the procedure on paying for Epogen administration. Effective for claims for monthly billing periods beginning on or after March 10, 1998, claims are to be paid when the three month rolling average exceeds 36.5%. Payment is based on the lower of the actual dosage billed for the current month or 80% of the prior month's allowable EPO dosage.

56. In July 1998, CMS issued a new Program Memorandum to its intermediaries and carriers:

> When indicated, conduct post-payment review of EPO by looking at a 90-day rolling average of hematocrit levels. Because of the natural variability in hematocrit levels and because we are encouraging practitioners to maintain a hematocrit level within the range of 33 to 36% as recommended by the Dialysis Outcomes Quality Initiative, use a threshold hematocrit value of 37.5% in targeting aberrant cases. Identify practitioners with an atypical number of patients with hematocrit levels above a 90-day rolling average of 37.5 % for routine medical review activities, such as educational efforts or pre-payment reviews.

57. CMS continued this directive in subsequent memoranda dated August 16, 2000, July 24, 2002, and September 5, 2003. Effective April 1, 2006, CMS implemented a new policy for the monitoring of Epogen usage: In order to allow for unanticipated increases in hematocrit, Medicare contractors will not be required to initiate monitoring until the hematocrit level reaches 39.0 (or hemoglobin of 13.0). For claims with hematocrit readings above the threshold of 39.0

(or hemoglobin of 13.0), the dose should be reduced by 25% over the preceding month in accordance with the FDA labeling.

58. Because of natural variability of hematocrit levels, CMS allowed reimbursement for claims that reported hematocrit levels up to 39%. For purposes of damages calculations herein, Relator has used hematocrit levels greater than 40%.

F. Studies Do Not Support the Use of Epogen to Increase Hematocrit Levels Above 36%

59. Not only is increasing an ESRD patient's hematocrit level above 36% contraindicated by the FDA label and DHHS guidelines, but it is wasteful and increases the risk to ESRD patients of adverse events, including death. Researchers, including Relator Cotter, have repeatedly found that no additional benefits in the quality of life for ESRD patients are achieved by increasing those patients' hematocrit levels above 36%. Moreover, having found that target hematocrit levels of approximately 36% are associated with poorer outcomes and increased risks among patients with anemia caused by chronic kidney disease, researchers have concluded that target hematocrit levels should not be higher than 36% and that Epogen should be discontinued, not merely reduced, when a patient's hematocrit levels reaches 39%.

60. These increased risks apply to both Epogen responders and Epogen non-responders. Pertaining to Epogen responders, the FDA label recommends that the use of Epogen be titrated upward until the patient reaches the recommended hematocrit/hemoglobin target. Once that target is achieved, the Epogen dosage should be titrated downward to maintain the patient within the recommended target range.

61. Epogen non-responders (also referred to as Epogen-resistant or Epogen hypo responsive patients), are patients for whom treatment with Epogen does not cause them to reach target hematocrit/hemoglobin levels as specified by the FDA. Regarding these patients, the FDA

recommends that the use of Epogen be suspended after 12 weeks of treatment if the patient's hematocrit/hemoglobin has not moved into the target range. If the provider chooses to ignore this guidance and continues to use prodigious amounts of Epogen, the patient will receive no justifiable medical benefit, but rather would be at a greater risk for an increase in adverse effects, as Relator Cotter has reported in the medical literature and to the FDA.

62. The increase in adverse risks associated with the overdosing of Epogen has been well known for some time. In 1993, Amgen began a clinical trial known as the "Normal Hematocrit Trial" in order to test the appropriateness of targeting patients to high hematocrit levels. In that trial, patients receiving Epogen who already had hematocrit levels of 30 to 33% were targeted to receive more Epogen until they reached a higher target range. In 1996, that trial was stopped early because of a 28% higher rate of deaths and nonfatal myocardial infarctions (heart attacks) in the high target group, a result contrary to the original hypothesis of the study.

G. Defendants Engage in Several Fraudulent Practice Patterns That Relate to Their Use of Epogen

63. Defendants knowingly engage in several Epogen practice patterns that are fraudulent and result in violations of the Federal False Claims Act and state false claims acts. These schemes involve (1) overdosing ESRD patients with Epogen beyond the FDA approved dose, (2) over-treating ESRD patients with Epogen beyond where the patient's hematocrit exceeds 36%, and (3) billing for use of vial over fill content, where Defendants illegally benefit from the fact that Amgen over fills vials of Epogen by between 10 and 20%, so as to provide free goods to Defendants, as a kickback and in direct contradiction of the Anti-Kickback Statute and applicable federal regulations. Most of these fraudulent schemes have their origins in Amgen's marketing schemes that promote the idea that high hematocrit levels in ESRD patients improve quality of life and the chance of improved survival for those patients. Nothing could be further

from the truth. Instead, high hematocrit levels in ESRD patients increases their risk of adverse events and death. Moreover, this idea directly contradicts the FDA label for Epogen, the DHHS guidelines for its use, and research studies on the overutilization of Epogen, most notably the terminated 1996 NHT clinical trial findings discussed above.

1. Overdosing of ESRD Patients

64. Overdosing refers to giving a patient too large a dose or too many doses of a medication. This complaint focuses on Defendants' practice of giving too large an Epogen dose to their patients, where the patient receives a dose of more than 300 U/kg of Epogen three times per week. This happens most frequently to patients who are considered Epogen resistant or Epogen non-responsive or hypo-responsive. Administration of such high doses of Epogen is in reckless disregard of the recognized standard of care as reflected in the FDA approved product label. Because there is no therapeutic value to be gained from administration of such high doses, one must conclude that such a practice pattern is only intended to generate income for the Defendants who provide and bill federal and state funded health programs for the Epogen. Overdosing is also incentivized by Amgen's sponsored discount and rebate programs that are related to the amount of Epogen used by Defendants. For purposes of single damages calculations herein, Relator required that claims have a service period of at least 8 days and have at least 3 Epogen administrations where the dose exceeded 300 units/kg.

2. Over-treating of ESRD Patients

65. Over-treating refers to administering any amount of Epogen where the patient's hematocrit exceeds a level of 36%. Those ESRD patients who respond to moderate Epogen doses and exceed a hematocrit of 36% are considered Epogen responsive patients. Over-treating is incentivized by Amgen's sponsored discount and rebate programs that are related to the

amount of Epogen used by Defendants. For purposes of single damages calculations herein, Relator has used hematocrit levels greater than 40%.

3. Use of Vial Over Fills by Defendants

66. Amgen over fills vials of Epogen by between 10 and 20%, also referred to as "free goods." This over fill amount allows Defendants to withdraw at least the volume described on the vial label. In many treatment sessions, Defendants use and bill Medicare and other federal and state funded health insurance programs for the free-goods (i.e. the vial over fill) they received from Amgen. This conduct, on the part of Amgen, was already the subject of a complaint and settlement (United States of America et al., ex rel. Westmoreland v. Amgen, Inc., et al. (Civil Action No. 06-10972-WGY) (D. Mass.). Defendants' receipt of those vial over fills from Amgen was not part of that litigation and is included in the complaint herein because the receipt of kickbacks by a provider who seeks reimbursement from a federal or state funded health insurance program is in direct contradiction of the Federal False Claims Act its state law counterparts, and federal regulations.

H. Defendants Over-Utilization of Epogen, Particularly at Dose Levels Above 300U/kg TIW

67. Through his own practice patterns research, Relator can prove that Defendants unnecessarily administered Epogen to patients with hematocrit levels above the target range. This phenomenon grew from 1997-2004 through 2005-2010. During those periods, the number of patients who received Epogen despite the fact that they were nonresponsive to the treatment increased among three Defendants: at Defendant Ridgewood, Epogen use rose from 887 claims to 1,127claims (a 27% increase); at Defendant Fresenius, Epogen use rose from 131,069 claims to 190,005 claims (a 45% increase); and at Defendant Newtown, Epogen use rose from 208 to 289 claims (a 39% increase). Also, during those periods, the number of patients who received

Epogen, despite the fact that they were nonresponsive to the treatment, slightly decreased by two Defendants: Defendant DCI reduced its claims from 20,025 to 15,742 (a 21 % decrease); and Defendant Nephrology Foundation reduced its claims from 273 to 241(a 12% decrease) although as to both DCI and Nephrology Foundation, their claim counts remained unacceptably high in relation to the FDA approved label.

68. From 1997 to 2010, Defendant Dialysis Centers submitted a total of 408,126 claims to Medicare and were paid $755 million for Epogen administered to patients who received Epogen in excessive amounts that were above the therapeutic range of 300units/kg TIW. As a result, these patients, who received such large medically unnecessary doses, were needlessly exposed to higher risks of adverse events.

69. Through his own practice patterns research, Relator can prove that Defendants' overdosing of patients with Epogen as described herein was contrary to the accepted standard of care and package labeling instructions, was potentially harmful to patients, was without medical necessity or patient need, and resulted in avoidable hospitalizations for treatment of adverse events described in the FDA approved product label, notably cardiovascular and thrombotic events and death. These hospitalizations resulted from Defendants misuse of Epogen. Specifically: costs related to Defendant Ridgewood's hospitalizations for overdosing patients with Epogen cost Medicare $14 million for 257 patients; costs related to Defendant Nephrology Foundation's hospitalizations for overdosing patients with Epogen cost Medicare $4 million for 76 patients; costs related to Defendant Newtown's hospitalizations for overdosing patients with Epogen cost Medicare $4 million for 93 patients; costs related to Defendant Fresenius' hospitalizations for overdosing patients with Epogen cost Medicare $2.06 billion for 75,140 patients; and costs related to Defendant DCI's hospitalizations for overdosing patients with

Epogen cost Medicare $200 million for 8,261 patients.

I. Defendants Over-Utilization of Epogen, Particularly at Hemocrit Levels Above 36%

70. Through his own practice patterns research, Relator can prove that Defendants unnecessarily administered Epogen to patients with hematocrit levels above the target range. This phenomenon grew exponentially from 1997-2004 through 2005-2010. During those periods, the number of patients who received Epogen despite the fact that they were non-responsive to the treatment increased among four Defendants: at Ridgewood, Epogen use rose from 1,005 to 1,713 claims (a 70% increase); at Fresenius, Epogen use rose from 321,464 to 386,578 claims (a 22% increase); at DCI, Epogen use rose from 8,751 to 19,604 claims (a 124% increase); and at Newtown, Epogen use rose from 335 to 590 claims (a 78% increase). Also during those periods, the number of patients who received Epogen despite the fact that they were nonresponsive to the treatment slightly decreased by one defendant. The Nephrology Foundation reduced their claims from 365 to 353(a 3% decrease) although their claim count remained unacceptably high in relation to the FDA approved label.

71. In 1998, dialysis centers nationwide had approximately 10% of all dialysis patients with hematocrit levels that exceeded 36%, but by 2000, 40% of all dialysis patients receiving Epogen had hematocrit levels above the target amount. During that same time period, there was also a significant increase in the average Epogen dose administered to dialysis patients. These increases occurred despite the fact that the 1996 "terminated" study (reported in 1998), the Normal Hematocrit Study showed that there was a higher risk of death or myocardial infarction in aiming for patients who were targeted to a hematocrit level of 42%.

72. From 1997 to 2010, Defendant Dialysis Centers submitted in total 781,869 claims to Medicare and were paid $0.303 billion dollars for Epogen administered to patients

whose hematocrit levels were in excess of 40%.

73. Administration of Epogen under these circumstances was contrary to the accepted standard of care and package labeling instructions, was potentially harmful to patients, was without medical necessity or patient need, and hence constituted false claims. Dialysis centers, including Defendants increased administration of Epogen to patients with hematocrit levels above the medically appropriate target levels as part of a scheme to increase revenue. The billings constituted false claims because they contained false certifications made by Defendants with regard to standard of care, medical necessity and patient need as well as with regard to the receipt of discounts, rebates and prohibited remuneration by Defendants. As such those billings were in direct contradiction of federal and state law, the FDA label, DHHS and CMS guidelines and the overwhelming weight of medical and scientific research regarding the use of Epogen.

74. Through his own practice patterns research, Relator can prove that Defendants' over treating of patients with Epogen as described herein was contrary to the accepted standard of care and package labeling instructions, was potentially harmful to patients, was without medical necessity or patient need, and resulted in avoidable hospitalizations for treatment of adverse events described in the FDA approved product label, notably, cardiovascular and thrombotic events and death. These hospitalizations resulted from Defendants misuse of Epogen. Specifically, costs related to Defendant Ridgewood's hospitalization for over treating patients with Epogen cost Medicare $17 million for 615 patients; costs related to Defendant Nephrology Foundation's hospitalizations for over treating patients with Epogen cost Medicare $5 million for 276 patients; costs related to Defendant Newtown's hospitalizations for over treating patients with Epogen cost Medicare $4 million for 237 patients; costs related to Defendant Fresenius's hospitalizations for over treating patients with Epogen cost Medicare $3

billion for 226,562 patients; and costs related to Defendant DCI's hospitalizations for over treating patients with Epogen cost Medicare $179 million for 18,801 patients.

V. APPLICABLE LAW

A. Federal & State False Claims Acts

75. Relator Dennis J. Cotter seeks to recover damages and civil penalties on behalf of the United States of America and the Plaintiff States arising from false and/or fraudulent records, statements and claims made, used and caused to be made, used or presented by Defendants and/or their agents, employees and co-conspirators in violation of the Federal Civil False Claims Act, 31 U.S.C. § 3729 et seq., as amended (the FCA) or (the Act) and its state-law counterparts: the District of Columbia Procurement Reform Amendment Act, D.C. Code Ann. §§ 1-1188.13 et seq.; the California False Claims Act, Cal. Gov Code § 12650 et seq.; the Colorado Medicaid False Claims Act, Colo. Rev. Stats. §§ 25.5-4-305 et seq.; the Connecticut False Claims Act, Conn. Gen. Stats. §§ 17b-301(a) et seq.; the Delaware False Claims and False Reporting Act, 6 Del. C. § 1201 et seq.; the Florida False Claims Act, Fla. Stat. Ann. § 68.081 et seq.; the Georgia State False Medicaid Claims Act, Ga. Code 49-4-168 et seq.; the Hawaii False Claims Act, Haw. Rev. Stat. § 661-21 et seq.; the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/1-8; the Indiana False Claims and Whistleblower Protection Act, Indiana Code 5-11-5.5 et seq.; the Louisiana False Claims Act, La. Rev. Stat. Ann. § 46:439.1 et seq.; the Maryland False Health Claims Act of 2010, Ann. Code of MD, §§ 2-601 et seq.; the Massachusetts False Claims Law, Mass. Gen. Laws ch. 12§ 5 et seq.; the Michigan Medicaid False Claim Act, MCL 400.611 § 10a et seq., Michigan Public Acts, 1977 PA 72, as amended by 1984 PA 333, as amended by 2005 PA 337, as amended by 2008 PA 421; the Minnesota False Claims Act, Minn. Stat. §§ 15C.01 et seq.; the Montana False Claims Act, 2005 Mont. Code, Ch. 465; the Nevada

False Claims Act, Nev. Rev. Stat. Ann. §§ 357.010 et seq.; the New Jersey False Claims Act, N.J. STAT. § 2A:32C-1; the New Mexico Medicaid False Claims Act, N.M. Stat. Ann.§ 27-2F-1 et seq.; the New Mexico Fraud Against Taxpayers Act , N.M. Stat. § 44-9-1 et seq.; the New York False Claims Act, State Finance Law. § 187 et seq.; the North Carolina False Claims Act, N.C. Gen. Stat §§ 1-605 et seq.; the Oklahoma Medicaid False Claims Act, 63 Okla. Stat. § 5053, et seq.; the Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1, et seq.; the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 71-5-181 et seq.; the Tennessee False Claims Act Tenn. Code Ann. § 4-18-101 et seq.; the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. §§ 36.001 et seq.; the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§ 8.01-216.1 et seq.; the Washington Medicaid Fraud False Claims Act, R.C.W. § 74.66 et seq. and the Wisconsin False Claims for Medical Assistance Act, WIS. STAT. § §20.931, et seq.

76. Pursuant to these laws, Relator brings this action on behalf of the United States and the Plaintiff States to recover the hundreds of millions of dollars Medicare, Medicaid, The Railroad Retirement Medicare Program, Federal Employees Health Benefit Programs, Tri-Care (formerly CHAMPUS), CHAMPVA, State Legal Immigrant Assistance Grants and the Indian Health Service have been fraudulently induced to pay as a result of false and/or fraudulent Epogen reimbursement claims submitted by, and caused to be submitted by Defendants.

77. The FCA provides that any person who knowingly submits, or causes the submission of, a false or fraudulent claim to the U.S. Government for payment or approval is liable for a civil penalty of up to $11,000 for each such claim, plus three times the amount of damages sustained by the Government. Liability attaches when a defendant knowingly seeks payment, or causes others to seek payment, from the Government that is unwarranted.

78. The FCA allows any person having information about a false or fraudulent claim against the Government to bring an action for himself and the Government, and to share in any recovery.

B. The Anti-Kickback Statute

79. The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2)(B), prohibits the solicitation or receipt of any remuneration (including kickbacks, bribes or rebates) directly or indirectly, overtly or covertly, in cash or in kind in return for the furnishing of any medical care or services for which payment may be made in whole or in part under any public assistance program. Compliance with the Anti-Kickback Statute is a condition precedent for reimbursement under Medicare and other federally-funded health programs. In other words, claims arising from an unlawful exchange violative of the Anti-Kickback Statute are, as a matter of law, ineligible for reimbursement and upon submission are false claims subject to the provisions of the Federal False Claims Act, 31 U.S.C. Section 3729 et seq.

C. The FDA Regulatory Scheme

80. Compliance with "all applicable Federal, state, and local laws and regulations pertaining to licensure and any other relevant health and safety requirements" is a condition of the Federal Government's payment for medical care provided by dialysis facilities. 42 C.F.R. § 405.2135 (2008); 42 C.F.R. § 494.20 (2008). The tender of the cost data and the certification in HCFA-265 are conditions of coverage. 42 C.F.R. § 405.2138 (2008); 42 C.F.R. § 413.20(b) (1996); 42 C.F.R. § 494.180(h)(3) (2008).

81. Each year, each Defendant named herein submits a cost report known as HCFA-265 to the Health Care Finance Administration (now known as CMS). The HCFA-265 report is required from all dialysis facilities that bill to the Federal Government, and the report includes a

certification of Defendants' adherence to federal laws and regulations.

82. Among the laws and regulations to which Defendants as Medicare providers certify their adherence are laws and regulations that require them to provide: (1) reasonable and necessary medical care, 42 U.S.C. § 1395y(a)(1)(A) and 42 C.F.R. § 411.15(k) (1990); (2) services and supplies that are in accordance with good medical practice and established quality, 32 C.F.R. § 199.4(d)(1) (1986); and (3) services and supplies the use of which are not tainted by the receipt of any type of remuneration, including a rebate. The Fraud and Abuse Statute 42 U.S.C. § 1320a-7b(b)(1) & 7a(a)(7). Moreover, in order to meet the general requirements for coverage under Medicare, Defendants may only bill for services or supplies which represent an expense incurred by them and may not bill for claims that do not represent a cost to them, like the amount of Epogen received by them in the form of Amgen's vial over fills. 42 C.F.R. 409.13 (1993).

83. Defendants, unable to bolster revenues for dialysis services because of Medicare's bundled rates, sought to increase revenues, by increasing their use of Epogen which could be billed separately and by billing for vial over fills, despite the fact that such actions were in violations of federal laws and regulations.

84. The natural, intended and foreseeable consequence of such unlawful, premeditated conduct caused Defendants to submit claims to publicly-funded health plans that were ineligible for reimbursement pursuant to these programs' regulations.

IV. GOVERNMENT FUNDED HEALTH CARE PROGRAMS DAMAGED BY PAYING FALSE EPOGEN CLAIMS

A. Medicare

85. Medicare is a government financial health insurance program administered by the Social Security Administration of the United States. The health insurance provided to

beneficiaries of the Medicare insurance program is paid in whole or in part by the United States. Medicare was promulgated to provide payment for medical services, durable medical equipment and other related health items for individuals 65 and over. Medicare also makes payment for certain health services provided to additional classes of individual health care patients pursuant to federal regulation.

86. As a direct, proximate and intended result of the conduct of the Defendants, alleged herein in violation of the Federal False Claims Act and the analogous laws of the Plaintiff States, the Medicare program has been damaged.

B. The Medicaid Act

87. Title XIX of the Social Security Act is a program that provides medical assistance for certain individuals and families with low incomes and resources. The program, known as Medicaid, became law in 1965 as a jointly funded cooperative venture between the Federal and State governments to assist States in the provision of adequate medical care to eligible needy Americans. Among the groups of people served by Medicaid are eligible low-income parents and children. Among the health benefits funded primarily by Medicaid, up until January 1, 2006, was funding for the prescription drug needs of the Program's beneficiaries.

88. A State must have a plan for medical assistance that has been approved by CMS, which administers the program on behalf of the Secretary of DHHS to participate in the Medicaid program. The state plan must specify, among other things, the specific kinds of medical care and services that will be covered. 42 U.S.C. § 1396a(a)(10) and (17). If the plan is approved by the Secretary, the State thereafter is eligible for federal financial participation, i.e., reimbursement by the federal government for a specified percentage of the amounts that qualify as medical assistance under the state plan. Id. at §§ 1396b(a)(I), 1396d(b).

89. States are accorded a broad measure of flexibility in tailoring the scope and coverage of their plans to meet the particular needs of their residents and their own budgetary and other circumstances. While the Medicaid Act requires States to provide certain basic services, the Act permits, but does not require, States to cover prescription drugs, although most States choose to do so. 42 U.S.C. § 1396d(a)(12).

90. In 1990, Congress enacted the Medicaid Drug Rebate Statute, codified at 42 U.S.C. §1396r-8, to "establish a rebate mechanism in order to give Medicaid the benefit of the best price for which a manufacturer sells a prescription drug to any public or private purchaser." H.R. Rep. No. 881, 101st Cong., 2d Sess. 96 (1990). That statute prohibits federal financial participation for covered outpatient drugs unless there is a rebate agreement in effect under section 1396r-8. See 42 U.S.C. §§ 1396b(i)(10)(A) and 1396r-8(a)(I). Once a drug manufacturer has entered into a rebate agreement for a covered outpatient drug, a State is generally required to cover that drug under the state plan.

91. However, there are several provisions of the Medicaid Act that permit a State to exclude or restrict coverage. 42 U.S.C. § 1396a(a)(54); H.R. Rep. No. 881 at 97,98. A State may restrict from coverage or exclude altogether certain drugs or classes of drugs, or certain medical uses, such as drugs used for, among other things, cosmetic purposes. 42 U.S.C. § 1396r-8(d)(l)(B)(ii). Relevant hereto is the provision which permits a State to exclude or restrict coverage of a drug where "the prescribed use is not for a medically accepted indication." 42 U.S.C. § 1396r-8(d)(l)(B)(i).

92. Under the statute, a "covered outpatient drug" includes a drug dispensed by prescription and approved as safe and effective under the Federal Food, Drug, and Cosmetic Act

("FDCA"), 21 U.S.C. §§ 355 & 357. It does not include "a drug or biological used for a medical indication which is not a medically accepted indication." 42 U.S.C. § 1396r-8(k)(2), (3).

93. The statute defines "medically accepted indication" as: any use for a covered outpatient drug which is approved [by the FDA, *i.e.* an on-label use], or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i) of this section. *Id.* at § 1396r-8(k)(6).

In addition to Medicaid, the Federal Government reimburses a portion of the cost of prescription drugs under several health care programs, including but not limited to Medicare, Medicare Part D, the Railroad Retirement Medicare Program, Federal Employees Health Benefit Programs, TRICARE (formerly CHAMPUS), CHAMPVA, the Federal Employees Compensation Act Program, the Bureau of Prisons, State Legal Immigrant Assistance Grants and the Indian Health Service, the Department of Defense, the Department of Labor, and the Public Health Service Entities. As alleged below, these programs operate in similar ways to the Medicare program. For example, the VA and CHAMPUS/TRICARE operate in substantially similar ways to the Medicare and Medicaid programs, but primarily for the benefit of military veterans, their spouses (or widowed spouses) and other beneficiaries.

C. The Railroad Retirement Medicare Program

94. The Railroad Retirement Medicare program is authorized by the Railroad Retirement Act of 1974, at U.S.C.A. § 231 et seq. It is administered through the United States Railroad Retirement Board (RRB) and furnishes Medicare coverage to retired railroad employees.

95. As a direct, proximate and intended result of the conduct of the Defendants, alleged herein in violation of the Federal False Claims Act and the analogous laws of the Plaintiff States, the RRB program has been damaged.

D. Federal Employee Health Benefit Plans

96. The Federal Employees Health Benefits Program (FEHBP) is administered by the United States Office of Personnel Management (OPM) pursuant to 5 U.S.C.A § 8901 et seq. and provides health care coverage to federal employees, retirees and their dependents and survivors.

97. As a direct, proximate and intended result of the conduct of the Defendants, alleged herein in violation of the Federal False Claims Act and the analogous laws of the Plaintiff States, the FEHBP program has been damaged.

E. TRICARE

98. The TRICARE program, formerly CHAMPUS, is administered by the United States Department of Defense through its component in agency, CHAMPUS, under the authority of 10 U.S.C.A. §§1701-1106. It is a health care program that provides for care in civilian facilities for members of the uniformed services and their dependents.

99. Pursuant to 38 U.S.C.A. § 8126, and the regulations based thereon, drugs furnished by drug manufactures to the Department of Defense must be furnished at the best price.

100. As a direct, proximate and intended result of the conduct of the Defendants, alleged herein in violation of the Federal False Claims Act and the analogous laws of the Plaintiff States, the TRICARE program has been damaged.

F. The Veterans Administration

101. The Civilian Health and Medical Program of the Department of Veterans Affairs (CHAMPVA) is a comprehensive health care program in which the VA shares the cost of covered health care services and supplies with eligible beneficiaries. The program is administered by Health Administration Center and its offices are located in Denver, Colorado. In general, the CHAMPVA program covers most health care services and supplies that are medically and psychologically necessary.

102. Due to the similarity between CHAMPVA and the Department of Defense (DOD) TRICARE program, the two are often mistaken for each other. CHAMPVA is a Department of Veterans Affairs program whereas TRICARE is a regionally managed health care program for active duty and retired members of the uniformed services, their families and survivors. In some cases a veteran may appear to be eligible for both/either program on paper. However, military retirees, or the spouse of a veteran who was killed in action, are and will always be TRICARE beneficiaries.

103. Pursuant to 38 U.S.C.A. § 8126, the regulations based thereon and contracts the Veterans Administration had with manufacturers, drugs furnished to the Veterans' Administration by drug manufacturers must be furnished at the best price.

104. The VA and CHAMPUS/TRICARE operate in substantially similar ways to the Medicare and Medicaid programs, but primarily for the benefit of military veterans, their spouses (or widowed spouses) and other beneficiaries.

105. As a direct, proximate and intended result of the conduct of the Defendants, alleged herein in violation of the Federal False Claims Act and the analogous laws of the Plaintiff States, the CHAMPVA program has been damaged.

G. Indian Health Service

106. The Indian Health Service is responsible for providing comprehensive health services to more than 1,400,000 Americans. It is administered by DHHS pursuant to 42 U.S.C.A. § 2008 et seq. The statute authorizes the Secretary to enter into contracts with independent providers to furnish health services to Native Americans whenever the Secretary determines that independent providers can better meet the population's need.

107. As a direct, proximate and intended result of the conduct of the Defendants, alleged herein in violation of the Federal False Claims Act and the analogous laws of the Plaintiff States, The Indian Health Service program has been damaged.

H. State Legal Immigrant Assistance Grants

108. Relator is informed, believes and based thereon alleges that the United States also furnishes funds which several States use to pay for prescription drugs pursuant to State Legal Immigrant Assistance Grants (SLIAG), 8 U.S.C.A § 1255A; 45 C.F.R. § 402.10.

VI. ALLEGATIONS

109. As early as 1997, Defendants began illegally overdosing and over-treating ESRD patients with amounts of the drug Epogen that exceeded the dosage amounts and treatment targets indicated in the FDA approved label, as well as DHHS and CMS guidelines; requirements demanded by state and federal compliances processes such as accreditation, credentialing, licensure and/or certification.

110. Overdosing patients with excessive amounts of Epogen was medically unnecessary and in direct contradiction of the applicable standard of care as established in the FDA label and DHHS and CMS guidelines. In fact, not only did ESRD patients not benefit from excessive amounts of Epogen, but such excessive amounts exposed ESRD patients to increased

risk for adverse effects and mortality.

111. Over-treating patients with Epogen by elevating their Hct above 36% was medically unnecessary and in direct contradiction of the applicable standard of care as established in the FDA label and DHHS and CMS guidelines. In fact, not only did ESRD patients not benefit from excessive hematocrit levels, but targeting and achieving levels above 36% exposed ESRD patients to increased risk for adverse effects and mortality.

112. Defendants knew or should have known that administering such excessive amounts of Epogen to ESRD patients both by overdosing and over-treating was medically unnecessary, in direct contradiction of the established standard of care and dangerous for patients, in that scientific studies going back as far as 1996 indicated the increased risks of adverse events, including death to ESRD patients who receive amounts of Epogen greater than indicated on the FDA approved label.

113. Defendants billed medically unnecessary and dangerous amounts of Epogen to state and federally funded health insurance programs in violation of the federal false claims act and its state law counterparts.

114. Defendants' actions also caused increased adverse health effects for ESRD patients, leading them to seek additional medical treatment and/or hospitalizations, often from Defendants themselves that was subsequently billed to state and federally funded health insurance.

115. From 1997 to 2010, Defendants knowingly received prohibited remuneration in the form of discounts, rebates and in-kind kickbacks in return for purchasing Epogen, while falsely certifying to the federal government that they were in compliance with all applicable laws and regulations pertaining to dialysis treatments.

116. Defendants profited from these prohibited remunerations at the expense of taxpayers and recipients of state and federally funded health insurance.

117. Defendants' actions have resulted in damage to taxpayers and in their illegal recovery of hundreds of millions of dollars from state and federally funded health insurance programs to which they are not entitled.

VII. CLAIMS FOR RELIEF

COUNT ONE

Violations of the Federal False Claims Act
31 U.S.C. § 3729(a)(2)(A)
Presenting or Causing to be Presented False Claims

118. Relator realleges and incorporates by reference each and every one of the foregoing paragraphs as if fully set forth herein.

119. This is a qui tam action brought by Relator and the United States to recover treble damages, civil penalties and the cost of this action, under the Federal False Claims Act, 31 U.S.C. §3730, for Defendant's violations of 31 U.S.C. § 3729 et seq.

120. The Federal False Claims Act, 31 U.S.C. § 3729(a)(2)(A) provides:

Liability for certain acts. Any person who--

(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval.

121. By virtue of the above-described acts, among others, Defendants knowingly presented or caused to be presented false or fraudulent claims for payment or approval, and continue to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the United States, in violation of 27 U.S.C. § 3729(a)(2)(A).

122. Those false claims include claims for reimbursement for medically unnecessary prescriptions of the drug Epogen which would not have been submitted, and thereafter paid by the United States, but for the illegal practices of Defendants described in this Complaint.

123. Plaintiff United States, unaware of the falsity of the claims that the Defendants made and caused others to make to the United States, and in reliance on the accuracy thereof, paid said Defendants and others for claims that would otherwise not have been allowed. These claims – prescription drug reimbursement claims for the drug Epogen – were false as that term is defined by the Federal False Claims Act in that they were ineligible for reimbursement as described herein.

124. For those claims that Defendants submitted or caused to be submitted, it was foreseeable and in fact the intended result that those claims would be submitted. Further, at all times relevant to the Complaint, Defendants acted with the requisite scienter.

125. By reason of Defendants' unlawful practices, substantial numbers of patients in the United States have been administered amounts of Epogen in excess of the amounts indicated on the FDA approved label and these practices thus provided substantial unlawful profits to Defendants.

126. The amounts of the false or fraudulent claims to the United States were material. Plaintiff United States, being unaware of the falsity of the claims and/or statements caused to be made by Defendants, and in reliance on the accuracy, thereof, paid and continues to pay Defendants for medically unnecessary and dangerous amounts of the drug Epogen.

127. It is believed that as a result of Defendants' violations of 31 U.S.C. § 3729 (a)(1)(A), the United States has suffered substantial losses in an amount that exceeds tens of millions of dollars, and is entitled to treble damages under the False Claims Act, to be

determined at trial, plus a civil penalty of $5,500 to $11,000 for each such false claim presented or caused to be presented by Defendants.

128. Relator Dennis J. Cotter is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the Federal False Claims Act on behalf of himself and the United States.

COUNT TWO

Violations of the Federal False Claims Act
31 U.S.C. § 3729(a)(2)(B)
Creation or Use of False Statements or Records Material to a False Claim

129. Relator realleges and incorporates by reference each and every one of the foregoing paragraphs as if fully set forth herein.

130. This is a qui tam action brought by Relator and the United States to recover treble damages, civil penalties and the cost of this action, under the Federal False Claims Act, 31 U.S.C. § 3730 for Defendant's violations of 31 U.S.C. § 3729 et seq.

131. The Federal False Claims Act, 31 U.S.C. § 3729(a)(2)(B) provides: Liability for certain acts. Any person who--

132. knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.

133. By virtue of the above-described acts, among others, Defendants knowingly made or used or caused to be made or used false records or statements material to false claims, and continue to do so, in violation of 27 U.S.C. § 3729(a)(2)(B).

134. Tens of thousands of claims for reimbursement for medically unnecessary amounts of Epogen would not have been submitted, and thereafter paid by the United States, but for the illegal practices of Defendants described in this Complaint including the creation and use

of false statements or records by Defendants.

135. Plaintiff United States, unaware of the falsity of the records and/or statements which the Defendants made or caused others to make were material to false claims, and in reliance on the accuracy thereof, paid Defendants and others for claims that would otherwise not have been allowed. These claims – prescription drug reimbursement claims for the drug Epogen – were false as that term is defined by the Federal False Claims Act in that they were ineligible for reimbursement as described herein.

136. For those records and/or statements that Defendants made or used or caused to be made or used, it was foreseeable and in fact the intended result that those statements and/or records would result in the payment to Defendants of false reimbursement claims for the drug Epogen. At all times relevant hereto, Defendants acted with the requisite scienter.

137. The amounts of the false or fraudulent claims caused to be paid pursuant to Defendants' false records and statements made or used or caused to be made or used to the United States were material. Relator United States, being unaware of the falsity of the records and/or statements made or caused to be made by Defendants, and in reliance on the accuracy thereof, paid claims that Defendants knew to be false, as they intended.

138. It is believed that as a result of Defendants' violations of 31 U.S.C. § 3729 (a)(1)(B), the United States has suffered substantial losses in an amount that exceeds tens of millions of dollars, and therefore is entitled to treble damages under the False Claims Act, to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each such false record and/or statement made or used or caused to be made or used by Defendants.

139. Relator Dennis J. Cotter is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the Federal False Claims Act on behalf of himself and the United States.

COUNT THREE

Violations of the Federal False Claims Act
31 U.S.C. § 3729(a)(2)(C) Conspiracy

140. Relator realleges and incorporates by reference each and every one of the foregoing paragraphs as if fully set forth herein.

141. This is a qui tam action brought by Relator and the United States to recover treble damages, civil penalties and the cost of this action, under the Federal False Claims Act, 31 U.S.C. §3730 for Defendant's violations of 31 U.S.C. § 3729 et seq.

142. The Federal False Claims Act, 31 U.S.C. § 3729(a)(2)(C) provides:

Liability for certain acts. Any person who—

> (C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G); ...is liable to the United States Government for a civil penalty of not less than $ 5,500 and not more than $11,000, plus 3 times the amount of damages which the Government sustains because of the act of that person, ...

143. In violation of 31 U.S.C. § 3729(a)(2)(C), by the foregoing acts and omissions, Defendants conspired with each other, Amgen, and others to violate 31 U.S.C. § 3729(a)(2)(A)(B) and (G) in violation of the False Claims Act, 31 U.S.C. § 3729(a)(2)(C).

144. By the foregoing acts and omissions, Defendants took actions in furtherance of their conspiracies, including but not limited to the receipt of substantial sums of monies and/or illegal kickbacks from Amgen. Indeed, Defendants conspired to violate the Anti-Kickback Statute 42 U.S.C. § 1328-7b(b) by unlawfully receiving incentives from Amgen to overdose and over-treat their ESRD patients with Epogen. Said actions constitute violations of the Federal

False Claims Act, 31 U.S.C. § 3729(a)(2)(C). Defendants committed other overt acts set forth above in furtherance of that conspiracy, all in violation of the laws of and causing damage to the United States.

145. As a consequence of Defendants' violations of 31 U.S.C. § 3729 (a)(2)(C), the United States has suffered substantial losses in an amount that exceeds tens of millions of dollars, and is entitled to treble damages under the False Claims Act, to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each such false claim Defendants conspired to get paid or allowed.

146. Relator Dennis J. Cotter is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the Federal False Claims Act on behalf of himself and the United States.

COUNT FOUR

District of Columbia False Claims Act D.C. Code Ann. § 2-331.02 et seq.

147. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

148. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the District of Columbia Government for payment or approval.

149. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the District of Columbia Government to approve and pay such false and fraudulent claims.

150. The District of Columbia Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by

Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

151. By reason of the Defendants' acts, the District of Columbia has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

152. Pursuant to D.C. Code Ann. § 2-308.14, the District of Columbia is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT FIVE

California False Claims Act
Cal. Govt. Code §§ 12651 et seq.

153. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

154. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the California State Government for payment or approval.

155. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the California State Government to approve and pay such false and fraudulent claims.

156. The California State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

157. By reason of the Defendants' acts, the State of California has been damaged, and

continues to be damaged, in substantial amounts to be determined at trial.

158. Pursuant to Cal. Govt. Code § 12651(a), the State of California is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT SIX

Colorado Medicaid False Claims Act
Colo Rev. Stats. § 25.5-4-305 et seq.

159. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

160. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Colorado State Government for payment or approval.

161. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Colorado State Government to approve and pay such false and fraudulent claims.

162. The Colorado State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

163. By reason of the Defendants' acts, the State of Colorado has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

164. Pursuant to Colorado Revised Statutes § 25.5-4-305 et seq., the State of Colorado is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for

each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT SEVEN

Connecticut Medicaid False Claims Act
Conn. Gen. Stats. § 17b-301(a) et seq.

165. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

166. This is a claim for treble damages and penalties under the Connecticut Medicaid False Claims Act, Conn. Gen. Stats. §§ 17b-301(a) et seq.

167. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, to an officer or employee of the State of Connecticut, false or fraudulent claims for payment or approval under medical assistance programs administered by the Department of Social Services.

168. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to secure the payment or approval by the State of Connecticut of such false or fraudulent claims under medical assistance programs administered by the Department of Social Services.

169. By virtue of the acts described above, Defendants conspired with each other and with others to defraud the State of Connecticut by securing the allowance or payment of a false or fraudulent claim under medical assistance programs administered by the Department of Social Services.

170. The Connecticut State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants'

illegal inducements and/or business practices.

171. By reason of the Defendants' acts, the State of Connecticut has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

172. The State of Connecticut is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT EIGHT

Delaware False Claims and Reporting Act
Del. Code Ann. tit. 6, § 1201 et seq.

173. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

174. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Delaware State Government for payment or approval.

175. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Delaware State Government to approve and pay such false and fraudulent claims.

176. The Delaware State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

177. By reason of the Defendants' acts, the State of Delaware has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

178. Pursuant to Del. Code Ann. tit. 6, § 1201(a), the State of Delaware is entitled to

three times the amount of actual damages plus the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT NINE

Florida False Claims Act
Fla. Stat. Ann. § 68.081 et seq.

179. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

180. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Florida State Government for payment or approval.

181. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Florida State Government to approve and pay such false and fraudulent claims.

182. The Florida State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

183. By reason of the Defendants' acts, the State of Florida has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

184. Pursuant to Fla. Stat. Ann. § 68.082(2), the State of Florida is entitled to three times the amount of actual damages plus the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT TEN

Georgia False Medicaid Claims Act
Ga. Code. Ann. § 49-4-168.1 et seq.

185. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

186. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Georgia State Government for payment or approval.

187. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Georgia State Government to approve and pay such false and fraudulent claims.

188. The Georgia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

189. By reason of the Defendants' acts, the State of Georgia has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

190. Pursuant to Ga. Code. Ann. § 49-4-168.1(a), the State of Georgia is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT ELEVEN

Hawaii False Claims Act
Haw. Rev. Stat. § 661-21 et seq.

191. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

192. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Hawaii State Government for payment or approval.

193. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Hawaii State Government to approve and pay such false and fraudulent claims.

194. The Hawaii State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

195. By reason of the Defendants' acts, the State of Hawaii has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

COUNT TWELVE

Illinois Whistleblower Reward and Protection Act
740 Ill. Comp. Stat. §§ 175/1 et seq.

196. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

197. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Illinois State Government for payment or approval.

198. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Illinois State Government to approve and pay such false and fraudulent claims.

199. The Illinois State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

200. By reason of the Defendants' acts, the State of Illinois has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

201. Pursuant to 740 Ill. Comp. Stat. § 175/3(a), the State of Illinois is entitled to three times the amount of actual damages plus the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT THIRTEEN

Indiana False Claims and Whistleblower Protection Act
Ind. Code §§ 5-11-5.5-1 et seq.

202. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

203. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Indiana State Government for payment or approval.

204. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Indiana State Government to approve and pay such false and fraudulent claims.

205. The Indiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

206. By reason of the Defendants' acts, the State of Indiana has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

COUNT FOURTEEN

Louisiana Medical Assistance Programs Integrity Law
La. Rev. Stat. Ann. §§ 46:439.1 et seq.

207. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

208. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Louisiana State Government for payment or approval.

209. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Louisiana State Government to approve and pay such false and fraudulent claims.

210. The Louisiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

211. By reason of the Defendants' acts, the State of Louisiana has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

212. Pursuant to La. Rev. Stat. Ann. § 46:438.6, the State of Louisiana is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT FIFTEEN

Maryland False Claims Act of 2010
Md. Code Ann. § 2-601 et seq.

213. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

214. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the State of Maryland for payment or approval.

215. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the State of Maryland to approve and pay such false and fraudulent claims.

216. The State of Maryland, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

217. By reason of the Defendants' acts, the State of Maryland has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

218. Pursuant to Ann. Code of MD §§ 2-601 (B)(1)(I) and (II) the State of Maryland is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for

each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT SIXTEEN

Massachusetts False Claims Law
Mass. Gen. Laws ch. 12, §§ 5A et seq.

219. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

220. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Massachusetts Commonwealth Government for payment or approval.

221. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Massachusetts Commonwealth Government to approve and pay such false and fraudulent claims.

222. The Massachusetts Commonwealth Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

223. By reason of the Defendants' acts, the Commonwealth of Massachusetts has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

224. Pursuant to Mass. Gen. Laws ch. 12, § 5B, the Commonwealth of Massachusetts is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT SEVENTEEN

Michigan Medicaid False Claims Act
Mich. Comp. Laws § 400.601 et seq.

225. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

226. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the State of Michigan for payment or approval.

227. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Michigan State Government to approve and pay such false and fraudulent claims.

228. The Michigan State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

229. By reason of the Defendants' acts, the State of Michigan has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

230. Pursuant to Mich. Stat. § 400.612, the State of Michigan is entitled to a civil penalty equal to the full amount received by the person benefiting from the fraud plus triple the amount of damages suffered by the state as a result of the conduct by the person.

COUNT EIGHTEEN

Minnesota False Claims Act
Minn. Stat. § 15C.01 et seq.

231. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

232. This is a claim for treble damages and penalties under the Minnesota False Claims Act, Minn, Stat, § 15C.01 et seq.

233. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, to an officer or employee of the State of Minnesota and/or political subdivisions, false or fraudulent claims for payment or approval.

234. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to get false or fraudulent claims paid ort approved by the State of Minnesota and/or its political subdivisions.

235. By virtue of the acts described above, Defendants knowingly conspired to either: 1) present a false or fraudulent claim to the State of Minnesota or a political subdivision for payment or approval; or, 2) makes, use, or cause to be made or used a false record or statement to obtain payment or approval of a false or fraudulent claim.

236. The Minnesota State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

237. By reason of the Defendants' acts, the State of Minnesota has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

238. The State of Minnesota is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT NINETEEN

Montana False Claims Act
Mont. Code Ann. § 17-8-401 et seq.

239. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

240. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the State of Montana for payment or approval.

241. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Montana State Government to approve and pay such false and fraudulent claims.

242. The Montana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

243. By reason of the Defendants' acts, the State of Montana has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

244. Pursuant to Mont. Code, Ch. 465, the State of Montana is entitled to a civil penalty equal to the full amount received by the person benefiting from the fraud plus triple the amount of damages suffered by the state as a result of the conduct by the person.

COUNT TWENTY

Nevada False Claims Act
Nev. Rev. Stat. § 357.010 et seq.

245. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

246. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Nevada State Government for payment or approval.

247. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Nevada State Government to approve and pay such false and fraudulent claims.

248. The Nevada State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

249. By reason of the Defendants' acts, the State of Nevada has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

COUNT TWENTY-ONE

New Jersey False Claims Act
N.J. Stat. Ann. §§ 2A:32C-1 et seq.

250. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

251. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the New Jersey State Government for payment or approval.

252. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Jersey State Government to approve and pay such false and fraudulent claims.

253. The New Jersey State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

254. By reason of the Defendants' acts, the State of New Jersey has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

255. Pursuant to N.J. Stat. Ann. § 2A:32C-3, the State of New Jersey is entitled to three times the amount of actual damages plus the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants. restates and incorporates each and every allegation above as if the same were fully set forth herein.

COUNT TWENTY-TWO

New Mexico Medicaid False Claims Act
N.M. Stat. Ann. § 27-14-1 et seq.
And New Mexico Fraud Against Tax Payers Act
N.M. Stat. Ann. § 44-9-1 et seq.

256. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

257. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the New Mexico State Government for payment or approval.

258. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Mexico State Government to approve and pay such false and fraudulent claims.

259. The New Mexico State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

260. By reason of the Defendants' acts, the State of New Mexico has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

261. Pursuant to N.M. Stat. Ann. § 44-9-3, the State of New Mexico is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT TWENTY-THREE

New York False Claims Act
N.Y. State Fin. Law § 187 et seq.

262. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

263. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the New York State Government for payment or approval.

264. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New York State Government to approve and pay such false and fraudulent claims.

265. The New York State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by

Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

266. By reason of the Defendants' acts, the State of New York has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

267. Pursuant to N.Y. State Fin. Law § 189, the State of New York is entitled to three times the amount of actual damages plus the maximum penalty of $12,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT TWENTY-FOUR

North Carolina False Claims Act
N.C. Gen. Stat. § 1-605 et seq.

268. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

269. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the North Carolina State Government for payment or approval.

270. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the North Carolina State Government to approve and pay such false and fraudulent claims.

271. By virtue of the acts described above, Defendants conspired with each other and with others to defraud North Carolina by inducing the North Carolina State Government to pay or approve false or fraudulent claims.

272. The North Carolina State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by

Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

273. By reason of the Defendants' acts, the State of North Carolina has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

274. Pursuant to N.C. Gen. Stat. §§ 1-605 et seq., the State of North Carolina is entitled to three times the amount of the actual damages plus the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT TWENTY-FIVE

Violations of the Oklahoma Medicaid False Claims Act
Okla. St. Ann. Tit. 63, § 5053 et seq.

275. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

276. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Oklahoma State Government for payment or approval.

277. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Oklahoma State Government to approve and pay such false and fraudulent claims.

278. The Oklahoma State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

279. By reason of Defendants' acts, the State of Oklahoma has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

280. Pursuant to 63 Okla. St. Ann. § 5053.1(B), the State of Oklahoma is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT TWENTY-SIX

The State False Claims Act (Rhode Island) R.I. Gen. Laws § 9-1.1-1 et seq.

281. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

282. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Rhode Island State Government for payment or approval.

283. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Rhode Island State Government to approve and pay such false and fraudulent claims.

284. The Rhode Island State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

285. By reason of the Defendants' acts, the State of Rhode Island has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

286. Pursuant to R.I. Gen. Laws § 9-1.1-3, the State of Rhode Island is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT TWENTY-SEVEN

Tennessee False Claims Act
Tenn. Code Ann. § 4-18-101 et seq.
and Tennessee Medicaid False Claims Act
Tenn. Code Ann. §§ 71-5-181 et seq.

287. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

288. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Tennessee State Government for payment or approval.

289. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Tennessee State Government to approve and pay such false and fraudulent claims.

290. The Tennessee State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

291. By reason of Defendants' acts, the State of Tennessee has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

292. Pursuant to Tenn. Code § 71-5-182(a)(1), the State of Tennessee is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT TWENTY-EIGHT

Texas Medicaid Fraud Prevention Law
Tex. Hum. Res. Code Ann. §§ 36.002 et seq.

293. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

294. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Texas State Government for payment or approval.

295. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Texas State Government to approve and pay such false and fraudulent claims.

296. The Texas State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

297. By reason of the Defendants' acts, the State of Texas has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

298. Pursuant to Tex. Hum. Res. Code Ann. § 36.002, the State of Texas is entitled to two times the amount of actual damages plus the maximum penalty of $15,000 for each and

every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT TWENTY-NINE

Virginia Fraud Against Taxpayers Act
Va. Code Ann. §§ 8.01-216.1 et seq.

299. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

300. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the State of Virginia for payment or approval.

301. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the State of Virginia to approve and pay such false and fraudulent claims.

302. The State of Virginia, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

303. By reason of Defendants' acts, the State of Virginia has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

304. Pursuant to Va. Code § 8.01-216.3(A), the State of Virginia is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT THIRTY

The Washington Medicaid Fraud False Claims Act
RCW 7466 et seq.

305. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

306. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Washington State Government for payment or approval.

307. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Washington State Government to approve and pay such false and fraudulent claims.

308. The Washington State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

309. By reason of the Defendants' acts, the State of Washington has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

310. Pursuant to Washington law, RCW 74.66, the State of Washington is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT THIRTY-ONE

Wisconsin False Claims for Medical Assistance Law
Wisc. Stat. §§ 20.931 et seq.

311. Relator restates and incorporates each and every allegation above as if the same were fully set forth herein.

312. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Wisconsin State Government for payment or approval.

313. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Wisconsin State Government to approve and pay such false and fraudulent claims.

314. The Wisconsin State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

315. By reason of the Defendants' acts, the State of Wisconsin has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

316. Pursuant to Wisc. Stat. § 20.931(2), the State of Wisconsin is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants. restate and incorporate each and every allegation above as if the same were fully set forth herein.

VIII. DEMANDS FOR RELIEF

317. WHEREFORE, Relator, on behalf of the United States Government and the Plaintiff States, demands judgment against the above-named Defendants as follows:

318. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the United States has sustained because of Defendants' actions, plus a civil penalty of not less than $5,500 and not more than $11,000 for each violation of 31 U.S.C. § 3729 et seq.;

319. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the District of Columbia has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of D.C. Code Ann. § 2-308.14(a) et seq.;

320. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of California has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Cal. Govt. Code § 12651(a) et seq.;

321. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Colorado has sustained because of Defendants' actions, plus the maximum civil penalty of $10,000 for each violation of the Colorado Medicaid False Claims Act, C.R.S. § 25.5-4-304, et seq.;

322. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Connecticut has sustained because of Defendants' actions, plus the maximum civil penalty of $10,000 for each violation of Conn. Gen. Stats. § 17b-301(a) et seq.;

323. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Delaware has sustained because of Defendants' actions, plus a civil penalty of $11,000 for each violation of 6 Del. C. § 1201(a) et seq.;

324. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Florida has sustained because of Defendants' actions, plus a civil penalty of $11,000 for each violation of Fla. Stat. Ann. § 68.082 et seq.;

325. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Georgia has sustained because of Defendants' actions, plus a civil penalty of $11,000 for each violation of O.C.G.A § 49-4-168 et seq.;

326. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Hawaii has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Haw. Rev. Stat. § 661-21(a) et seq.;

327. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Illinois has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of 740 Ill. Comp. Stat. § 175/3(a) et seq.;

328. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Indiana has sustained because of Defendants' actions, plus civil penalties for each violation of I.C. § 5-11-5.5 et seq.;

329. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Louisiana has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of La. Rev. Stat. § 46:438.6 et seq.;

330. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Maryland has sustained because of Defendants'

actions, plus a civil penalty of $10,000 for each violation of Md. Code Ann. § 2-601 et seq;

331. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Massachusetts has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Mass. Gen. L. Ch. 12 § 5B et seq.;

332. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Michigan has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Mich. Comp. Laws § 400.612 et seq.;

333. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Minnesota has sustained because of Defendants' actions, plus the maximum civil penalty of $11,000 for each violation of Minn. Stat. § 15C.01 et seq.;

334. that this court enter judgment against Defendants in an amount equal to three times the amount of damages Montana has sustained because of the Defendants' actions, plus a civil penalty of $10,000 for each violation of the Montana False Claims Act, Mont. Code Ann., § 17-8-401 et seq.;

335. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Nevada has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Nev. Rev. Stat. Ann. § 357.040(1) et seq.;

336. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of New Jersey has sustained because of Defendants' actions, plus civil penalties for each violation of N.J. Stat. § 2A:32C-1 et seq.;

337. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of New Mexico has sustained because of Defendants' actions, plus civil penalties for each violation of N.M. Stat. Ann. § 27-14-1 et seq.; and N.M. Stat. Ann. § 44-9-1 et seq.;

338. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of New York has sustained because of Defendants' actions, plus a civil penalty of $12,000 for each violation of N.Y. State Fin. § 187 et seq.;

339. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of North Carolina has sustained because of Defendants' actions plus a civil penalty of $11,000 for each violation of N.C. Gen. Stat. § 1-605 et seq.;

340. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Oklahoma has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Okla. St. Ann. tit. 63, § 5053.1(B) et seq.;

341. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Rhode Island has sustained because of Defendants' actions, plus civil penalties for each violation of R.I. Gen. Laws § 9-1.1-1 et seq.;

342. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Tennessee has sustained because of Defendants' actions, plus a civil penalty for each violation of Tenn. Code Ann. § 71-5-182(a) et seq.;

343. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Texas has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Tex. Hum. Res. Code Ann. § 36.052 et seq.;

344. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the Commonwealth of Virginia has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Va. Code Ann. § 8.01-216.3(a) et seq.;

345. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages Washington has sustained because of Defendants' actions, plus a civil penalty of $11,000 for each violation of R.C.W. § 74.66 et seq.;

346. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages Wisconsin has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of the Wis. Stat. § 20.931 et seq.;

347. that this Court enter judgment against Defendants in an amount equal to three times the amount of each claim for compensation, plus a civil penalty of $10,000 for each claim under Cal. Ins. Code § 1871.7;

348. that this Court enter judgment against Defendants in an amount equal to three times the amount of each claim for compensation, plus a civil penalty of $10,000 for each claim under Ill. Comp. Stat. § 92/5;

349. that Relator be awarded the maximum amount allowed pursuant to § 3730(d) of the Federal False Claims Act, and the equivalent provisions of the state statutes set forth above;

350. that Relator be awarded all costs of this action, including attorneys' fees and expenses;

351. that this Court enter judgment against Defendants for violations of the FCA;

352. that the United States and the Plaintiff States recover such other relief as the Court deems just and proper or that is necessary to make the United States and the Plaintiff States whole; and

353. that Relator recovers such other relief as the Court deems just and proper or that is necessary to make Relator whole.

TRIAL BY JURY

Relator hereby demands a trial by jury as to all issues.

Dated: February 7, 2013

BY: /s/ Richard F. Bernstein

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